

AMENDMENTS TO THE SPECIFICATION:

Please amend page 1 of the specification as follows:

The present application is a divisional patent application which claims priority under 35 U.S.C. §120 and §121 to U.S. Serial No. 09/194,267 filed March 22, 1999, which claims priority under 35 U.S.C. §119 to PCT/GB/01426 filed on May 23, 1997, British Application No. 9705498.5 filed March 17, 1997, and British Application No. 9610944.2 filed May 24, 1996.

The present invention relates to a compound. In addition, the present invention relates to processes for making the compound and to the use of that compound in therapy, in particular gene therapy (especially gene transfer).

One aspect of gene therapy involves the introduction of foreign nucleic acid (such as DNA) into cells, so that its expressed protein may carry out a desired therapeutic function.¹

Examples of this type of therapy include the insertion of TK, TSG or ILG genes to treat cancer; the insertion of the CFTR gene to treat cystic fibrosis; the insertion of NGF, TH or LDL genes to treat neurodegenerative and cardiovascular disorders; the insertion of the IL-1 antagonist gene to treat rheumatoid arthritis; the insertion of HIV antigens and the TK gene to treat AIDS and CMV infections; the insertion of antigens and cytokines to act as vaccines; and the insertion of β -globin to treat haemoglobinopathic conditions, such as thalassaemias.

Many current gene therapy studies utilise adenoviral gene vectors – such as Ad3 or Ad5 – or other gene vectors. However, serious problems have been associated with their use.² This has prompted the development of less hazardous, non-viral approaches to gene transfer.³

A non-viral transfer system of great potential involves the use of cationic liposomes. In this regard, cationic liposomes – which usually consist of a neutral phospholipid and a cationic lipid – have been used to transfer DNA⁴, mRNA⁵, antisense oligonucleotides⁶, proteins⁷, and drugs⁸ into cells. A number of cationic liposomes are commercially available^{4,9} and many new cationic lipids have recently been synthesised.¹⁰ The efficacy of these liposomes has been illustrated by both *in vitro*⁴ and *in vivo*¹¹.

A neutral phospholipid useful in the preparation of a cationic liposome is *N*-[1-(2,3-